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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,990	11/21/2003	Horst Heirler	028622-0125	8166

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/717,990	HEIRLER, HORST	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6 and 8-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6 and 8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 3-6 and 8-20 are presented for examination.

Applicant's Amendment filed November 2, 2007 has been received and entered into the present application.

Claims 1, 3-6 and 8-20 are pending and under examination. Claims 1, 12 and 17 are amended.

Applicant's arguments, filed November 2, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 and 6 remain rejected under 35 U.S.C. 102(b) as being anticipated by Alexander et al. (EP 0691079 A2l 1996) in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; abstract only), cited to show a fact, each already of record, for the reasons of record set forth at pages 7-9 of the previous Office Action dated May 2, 2007, of which said reasons are herein incorporated by reference.

Amended claim 11 obviates the instant rejection under 35 U.S.C. 102(b) over such claims, since claim 11 (from which claim 12 depends) now requires both mono- and diglycerides, as well as butter

flavorings, which are each not explicitly described in the teachings of Alexander et al. For this reason, claims 11-12 are **withdrawn** from the present rejection.

Applicant traverses the instant rejection, stating that Alexander et al. fails to teach or suggest a composition containing a fatty acid comprising eicosapentaenoic acid and/or docosahexaenoic acid and Brenna does not remedy this deficiency in Alexander because the reference also fails to teach or suggest a composition comprising eicosapentaenoic acid and/or docosahexaenoic acid. Applicant submits that the conversion of alpha-linolenic acid to docosahexaenoic acid is effected very slowly in the body with the help of desaturase enzymes, "which are found in many tissues" (p.8, Remarks). Still further, Applicant submits that the compound of Alexander et al. does not contain any desaturase enzyme that would allow this conversion to take place.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

It is acknowledged that Alexander et al. does not *explicitly* teach the presence of eicosapentaenoic and/or docosahexaenoic acid in the disclosed composition containing, among other elements, alpha-linolenic acid (see p.4, l.10-26 of Alexander et al.). However, this gap in the reference is properly filled with recourse to extrinsic evidence in accordance with MPEP §2131.01, which states that a secondary reference may be properly applied in a rejection under 35 U.S.C. 102 as long as the second reference is cited to: (1) Prove the primary reference contains an "enabled disclosure"; (2) Explain the meaning of a term used in the primary reference; or (3) Show that a characteristic not disclosed in the reference is inherent.

In the instant case, Brenna is cited to show that a characteristic not disclosed in the reference to Alexander et al. is necessarily present, namely, that alpha-linolenic acid is an omega-3 fatty acid precursor that is converted into the omega-3 long-chain polyunsaturated fatty acid docosahexaenoic and/or eicosapentaenoic acid and, thus, the very administration of plant oils containing alpha-linolenic acid necessarily contains both docosahexaenoic and/or eicosapentaenoic because at least some part of the

alpha-linolenic acid will be converted to either or both of these products, absent factual evidence to the contrary. Since the citation to Brenna is proper and firmly grounded in the teachings of the MPEP at §2131.01, the fact that the secondary reference fails to provide a teaching of a fatty acid composition as presently claimed is immaterial to the instant rejection because the reference was cited to show a fact missing (but well known in the art) from the primary reference to Alexander et al. and, therefore, is not required to itself anticipate each and every element of the claimed invention.

Moreover, Applicant advances the reason that, because the composition of Alexander et al. fails to contain any desaturase enzymes, the alpha-linolenic acid contained within the composition of Alexander et al. would not be converted (at least in part) to eicosapentanoic and/or docosahexaenoic acid. However, as evidenced both by Brenna and also Applicant's remarks (which admit that desaturase enzymes are found in many tissues; see Remarks, p.8), the body itself is capable of converting alpha-linolenic acid to its conversion product docosahexaenoic acid (in a quantity of below 5%, depending on the concentration of n-6 fatty acids and long-chain polyunsaturated fatty acids; see Brenna). In view of this fact, the very administration of alpha-linolenic acid would necessarily result in the production of, e.g., docosahexaenoic acid, because DHA is a known metabolite produced via the conversion of alpha-linolenic acid. Furthermore, it is noted that "administration" of the claimed fatty acid product as required by claim 1 is not limited in any fashion and is, thus, understood to mean that the therapy occurs anywhere within the body. Such an interpretation is sufficiently broad enough to encompass situations wherein the introduction of alpha-linolenic acid (as part of the fatty acid composition of Alexander et al.) into the body would, by the time it reached, e.g., the stomach, had already resulted in the formation of its conversion product DHA. In other words, the claims as presently written read upon any means to introduce DHA to the host, which includes the introduction of DHA via the conversion of alpha-linolenic acid in the body.

For these reasons, and those previously made of record at pages 7-9 of the previous Office Action dated May 2, 2007, rejection of claims 1, 3 and 6 remains proper and is **maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 6, 9 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (EP 0691079 A2; 1996) in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132; March 2002; abstract only), cited to show a fact, each already of record, in view of newly cited Harries (U.S. Patent No. 3,995,069; 1976), for the reasons of record set forth at pages 9-12 of the previous Office Action dated May 2, 2007, of which said reasons are herein incorporated by reference.

Newly amended claim 11 now requires the presence of mono- and diglycerides of edible fatty acids, fat-soluble vitamins, beta-carotene and butter flavorings in the claimed fatty acid composition. Alexander et al. teaches the inclusion of vitamins A, C, D and E into the composition (i.e., fat-soluble vitamins, see claim 12; Table, p.6-7) and beta-carotene (Table, p.6-7). Though Alexander et al. does not explicitly teach the incorporation of mono- and diglycerides into the disclosed fatty acid composition, mono- and diglycerides were both well known in the art as effective emulsifying agents, particularly for use in foodstuffs (see abstract of Harries, USPN 3,995,069) and, therefore, the incorporation of such agents into the fatty acid composition of Alexander et al. would have been *prima facie* obvious in view of the fact that the composition of Alexander et al. is an aqueous formulation containing a significant portion

of fat. Such a person would have been motivated to incorporate mono- and diglycerides into the composition of Alexander et al. to effect emulsification of the aqueous and fat phases to produce a relatively homogeneous mixture for administration.

Newly amended claim 11 also requires the presence of butter flavorings in the claimed fatty acid composition. Though Alexander et al. does not explicitly teach this element of the composition, one of ordinary skill in the art would have found it *prim a facie* obvious to incorporate appropriate flavorings, including butter flavor, into the disclosed diabetic supplement of Alexander et al. to enhance the taste of the composition. Such a person would have been motivated to do so in order to improve the palatability of the composition and, thus, to improve patient compliance with a regimen of administration as a result of the superior taste.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Alexander et al. and Brenna fail to teach or suggest the invention of claims 1, 3, 6 and 11-12 as demonstrated above under 35 U.S.C. 102(b). Specifically, Applicant alleges that Alexander et al. fails to teach or suggest a composition containing a fatty acid comprising eicosapentaenoic acid and/or docosahexaenoic acid and Brenna does not remedy this deficiency in Alexander because the reference also fails to teach or suggest a composition comprising eicosapentaenoic acid and/or docosahexaenoic acid. Applicant submits that the conversion of alpha-linolenic acid to docosahexaenoic acid is effected very slowly in the body with the help of desaturase enzymes, "which are found in many tissues" (p.8, Remarks). Still further, Applicant submits that the compound of Alexander et al. does not contain any desaturase enzyme that would allow this conversion to take place.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

It is acknowledged that Alexander et al. does not *explicitly* teach the presence of eicosapentaenoic

and/or docosahexaenoic acid in the disclosed composition containing, among other elements, alpha-linolenic acid (see p.4, l.10-26 of Alexander et al.). However, this gap in the reference is properly filled with recourse to extrinsic evidence in accordance with MPEP §2131.01, which states that a secondary reference may be properly applied in a rejection under 35 U.S.C. 102 as long as the second reference is cited to: (1) Prove the primary reference contains an "enabled disclosure"; (2) Explain the meaning of a term used in the primary reference; or (3) Show that a characteristic not disclosed in the reference is inherent.

In the instant case, Brenna is cited to show that a characteristic not disclosed in the reference to Alexander et al. is necessarily present, namely, that alpha-linolenic acid is an omega-3 fatty acid precursor that is converted into the omega-3 long-chain polyunsaturated fatty acid docosahexaenoic and/or eicosapentaenoic acid and, thus, the very administration of plant oils containing alpha-linolenic acid necessarily contains both docosahexaenoic and/or eicosapentaenoic because at least some part of the alpha-linolenic acid will be converted to either or both of these products, absent factual evidence to the contrary. Since the citation to Brenna is proper and firmly grounded in the teachings of the MPEP at §2131.01, the fact that the secondary reference fails to provide a teaching of a fatty acid composition as presently claimed is immaterial to the instant rejection because the reference was cited to show a fact missing (but well known in the art) from the primary reference to Alexander et al. and, therefore, is not required to itself anticipate each and every element of the claimed invention.

Moreover, Applicant advances the reason that, because the composition of Alexander et al. fails to contain any desaturase enzymes, the alpha-linolenic acid contained within the composition of Alexander et al. would not be converted (at least in part) to eicosapentanoic and/or docosahexaenoic acid. However, as evidenced both by Brenna and also Applicant's remarks (which admit that desaturase enzymes are found in many tissues; see Remarks, p.8), the body itself is capable of converting alpha-linolenic acid to its conversion product docosahexaenoic acid (in a quantity of below 5%, depending on

the concentration of n-6 fatty acids and long-chain polyunsaturated fatty acids; see Brenna). In view of this fact, the very administration of alpha-linolenic acid would necessarily result in the production of, e.g., docosahexaenoic acid, because DHA is a known metabolite produced via the conversion of alpha-linolenic acid. Furthermore, it is noted that "administration" of the claimed fatty acid product as required by claim 1 is not limited in any fashion and is, thus, understood to mean that the therapy occurs anywhere within the body. Such an interpretation is sufficiently broad enough to encompass situations wherein the introduction of alpha-linolenic acid (as part of the fatty acid composition of Alexander et al.) into the body would, by the time it reached, e.g., the stomach, had already resulted in the formation of its conversion product DHA. In other words, the claims as presently written read upon any means to introduce DHA to the host, which includes the introduction of DHA via the conversion of alpha-linolenic acid in the body.

For these reasons, and those previously made of record at pages 9-12 of the previous Office Action dated May 2, 2007, rejection of claims 1, 3, 6, 9 and 11-19 remains proper and is **maintained**.

Claims 1, 3-6, 8-10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (EP 0691079 A2; 1996) in light of Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; abstract only), cited to show a fact, in view of Madigan et al. ("Dietary Unsaturated Fatty Acids in Type 2 Diabetes", *Diabetes Care*, 23:1472-1477; 2000), Heine et al. ("Linoleic-Acid Enriched Diet: Long-Term Effects on Serum Lipoprotein and Apolipoprotein Concentrations and Insulin Sensitivity in Noninsulin-Dependent Diabetic Patients", *Am J Clin Nutr*, 1989 Mar; 49(3):448-456; Abstract Only) and The Merck Index ("Citric Acid", Monograph 2328, 1989; page 363), each already of record, for the reasons of record set forth at

pages 12-15 of the previous Office Action dated May 2, 2007, of which said reasons are herein incorporated by reference.

Applicant traverses the instant rejection, stating again that the references to Alexander et al. and Brenna fail to teach of suggest a nutritional composition comprising eicosapentaenoic and/or docosahexaenoic acid. Applicant submits that, while Heine et al. may teach that a linoleic-enriched diet in patients with NIDD causes a less atherogenic lipoprotein profile than a diet with a low polyunsaturated to saturated fat ratio, it teaches that a linoleic-enriched diet does not influence glycemic control and carbohydrate tolerance. Still further, Applicant states that Madigan et al. teaches away from the claimed invention because the reference allegedly discloses that a linoleic acid-enriched diet may not be the best option for people with type 2 diabetes, since a linoleic acid-rich diet is associated with increased fasting insulin and glucose levels, increase postprandial lipoproteins and significantly higher plasma and LDL cholesterol levels, all of which are associated with atherosclerotic risk.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

First, in response to Applicant's remarks regarding a lack of teaching or suggestion in Alexander et al. and Brenna of a nutritional composition comprising eicosapentanoic and/or docosahexaenoic acid, Applicant's attention is directed *supra* to the response(s) provided to the previous rejections under 35 U.S.C. 102(b) and/or 35 U.S.C. 103(a), of which said reasons will not be repeated herein so as not to burden the record.

Second, with regard to Applicant's allegations of a lack of motivation to use a linoleic-enriched diet in a diabetic patient, Applicant is first reminded that Madigan et al. discloses a linoleic-enriched diet as "not the *best* option" (emphasis added) for people with type 2 diabetes. Though this may be a non-preferred manner for treating diabetic patients due to the fact that it does not provide a particularly effective means of glycemic control, Applicant is reminded that (1) a preferred embodiment (in this case, an *oleic acid-rich diet*) does not constitute a teaching away from a non-preferred embodiment (in this

case, a *linoleic acid-rich diet*; see MPEP §2123) and (2) Heine et al. clearly supports the conclusion that, despite its lack of effect in providing glycemic control and/or carbohydrate tolerance, use of a linoleic acid-enriched diet in a diabetic patient does, in fact, provide at least some reduction in the atherogenic lipoprotein profile. Given these facts, one of ordinary skill in the art would have been motivated to combine a greater amount of linoleic acid (than what is provided for in Alexander et al.) with an even higher proportion of oleic acid because each of linoleic acid and oleic acid were well known in the art to provide some atherosclerotic protection (of which atherosclerosis is a known and potentially deadly complication of diabetes) by reducing serum lipoproteins. Further, since oleic acid was known to be *more effective* in this respect than linoleic acid, it logically follows that the artisan would have been motivated to use an even greater amount of oleic acid than linoleic acid to provide the atherosclerotic protecting effects while providing improved diabetic glycemic control.

Furthermore, whatever lack of efficacy a linoleic acid-enriched diet has in providing glycemic control to a diabetic patient still does not constitute a teaching away from its use with the fatty acid composition of Alexander et al. because Alexander et al. explicitly teaches the function of the disclosed composition as a whole as effective to reduce sensitivity to dose and timing of insulin so as to reduce postprandial serum glucose via improved tolerance, metabolic and glucose management and insulin requirements (p.3, l.55-58 of Alexander et al.). Accordingly, one of ordinary skill in the art at the time of the invention would have expected that the overall effect of the diabetic supplement of Alexander et al. in providing *improved* glycemic control in a diabetic patient would have negated the asserted lack of efficacy of linoleic acid in providing effective glycemic control in a diabetic patient. In light of these facts, the skilled artisan would have considered such a combination to have at least *reasonable expectation* of successfully providing effective nutritional supplementation to a diabetic patient with the added benefit of providing effective atherosclerotic protection by reducing serum lipoproteins, absent factual evidence to the contrary. Note that *absolute predictability* is not required to find obviousness

under 35 U.S.C. 103(a), just a *reasonable expectation of success* (see MPEP §2143.02).

In view of the foregoing reasons, and those already of record, it is maintained that the claims are *prima facie* obvious in light of the cited prior art.

For these reasons, and those previously made of record at pages 12-15 of the previous Office Action dated May 2, 2007, rejection of claims 1, 3-6, 8-10 and 20 remains proper and is **maintained**.

Conclusion

Rejection of claims 1, 3-6 and 8-20 remains proper and is **maintained**.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

January 9, 2008

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER